

Complete Summary

GUIDELINE TITLE

Guideline for the management of clinically localized prostate cancer: 2007 update.

BIBLIOGRAPHIC SOURCE(S)

Prostate Cancer Clinical Guideline Update Panel. Guideline for the management of clinically localized prostate cancer: 2007 update. Linthicum (MD): American Urological Association Education and Research, Inc.; 2007. 82 p. [123 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Urological Association (AUA), Prostate Cancer Clinical Guidelines Panel. Report on the management of clinically localized prostate cancer. Baltimore (MD): American Urological Association, Inc; 1995. 49 p. (Clinical practice guidelines; no. 1/95).

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SCOPE

DISEASE/CONDITION(S)

Locally confined prostate cancer

GUIDELINE CATEGORY

Management
 Treatment

CLINICAL SPECIALTY

Oncology
Radiation Oncology
Urology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To provide medical practitioners with a consensus of principles and strategies for the treatment of clinically localized prostate cancer
- To update the 1995 Guideline for the Management of Clinically Localized Prostate Cancer

TARGET POPULATION

Men with clinically localized stage T1 to T2 prostate cancer with no regional lymph node or distant metastases (T1 to T2N0-NxM0)

Note: The recommendations were not developed for patients with stage T3-T4 disease.

INTERVENTIONS AND PRACTICES CONSIDERED

1. Initial evaluation (including prostate-specific antigen, digital rectal exam, biopsy, tumor staging and grading)
2. Watchful waiting and active surveillance
3. Interstitial prostate brachytherapy
4. External beam radiotherapy
5. Radical prostatectomy
6. Primary hormonal therapy (including androgen deprivation therapy, e.g., bicalutamide)

MAJOR OUTCOMES CONSIDERED

Patient survival, disease-free survival and progression to metastatic disease

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Due to the lack of randomized studies with sufficient follow-up to accurately assess treatment impact on patient survival, the 1995 Guideline Panel was unable to achieve its primary goal of publishing summary outcomes tables that compared the available treatments for localized prostate cancer. Five years hence, with the subsequent development of measures of biochemical progression, meaningful risk

categories, and patient quality-of-life measures as well as the availability of a more careful and extensive collection of outcomes data, a *Guideline Update Panel* was appointed. It appeared that useful outcomes tables might be generated at this time. The Panel began a literature search and data extraction to capture clinical treatment outcomes for patients with clinical stage T1 to T2N0M0 prostate cancer.

Search and Data Extraction

A series of four PubMed searches was conducted between May 2001 and April 2004 to capture articles published from 1991 through early 2004. The search terms included the medical subject heading (MeSH) Major Topics of **prostate cancer** and **prostatic neoplasms** and were limited to human subjects and to the English language. The resulting 13,888 citations and abstracts were screened for articles reporting outcomes (efficacy or side effects) of prostate cancer treatment in patients with clinical stage T1 or T2 disease (see Figure 1; Appendix 6 of the original guideline document).

Articles were rejected if patients with higher stage disease were included in the study and the outcomes were not stratified by stage. The 592 articles meeting these inclusion criteria were retrieved for data extraction.

NUMBER OF SOURCE DOCUMENTS

- 13,888 identified on PubMed searches
- 1,764 articles met initial screening criteria
- 592 met criteria for extraction
- 436 articles accepted

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

An extraction form (see Appendix 7 of the original guideline document) was developed that included patient characteristics, treatments, and outcomes data such as the definition of biochemical progression used in the study, survival, disease-free survival, and progression to invasive disease (refer to the Glossary in Appendix 3 of the original guideline document). During the extraction process, articles again were scanned for relevance and were rejected if outcomes were not reported or stratified for clinically localized disease or if outcomes in fewer than 50

patients were reported. Detailed and repeated training of extractors was performed both by the American Urological Association (AUA) guidelines staff and consultants and by members of the Minneapolis Veterans Administration Center for Chronic Disease Outcomes Research, Cochrane Review Group in Prostate Diseases. After the data extraction from individual articles, several data quality assurance audits were performed. Double extraction of articles was not routinely performed. Weekly meetings with the data-extraction team were held to review the extraction process and to address questions. At that time, a 10% sample of articles was selected, and the extracted data, in the presence of the original article, were reevaluated by two other members, including the senior research associate and Dr. Wilt, the project director. Discrepancies and their reasons (e.g., errors of omission, commission, and interpretation) were resolved by discussion. Values that appeared to be out of bounds on any article (e.g., very low age, impossible histologic scores) were noted. Additional quality checks were performed by members of the AUA guidelines staff, consultants, and Panel members, discrepancies were noted, and feedback was provided to extractors and resolved through additional discussion and review. Upon completion, data from 592 articles were extracted and entered into a Microsoft Access© (Microsoft, Redmond, WA) database that serves as the basis for the results reported herein (see Appendix 8 of the original guideline document).

The Guideline Update Panel met multiple times, both face-to-face and by teleconference, to review the extracted data. Attempts were made to delete reports/studies of insufficient quality (e.g., those that did not stratify patients appropriately or lacked data concerning key outcomes) and to determine which reports/studies overlapped so that duplicate data for the same patients would not be included. In addition to evidence tables, a large number of graphic displays of the extracted data were reviewed by the Panel. Displays of efficacy data were based primarily on prostate-specific antigen (PSA) recurrence due to the lack of long-term follow-up. The variation in definition of PSA recurrence among the studies caused considerable variation in the results as illustrated in Figure 2 and Appendix 11 of the original guideline document.

Summarizing data concerning complications presented two problems. First, methods of categorizing complications were not standardized across studies. For example, some studies reported percentages of patients with "gastrointestinal complications" while others reported separate percentages for "nausea," "vomiting," and "diarrhea." Second, not all studies reported complications by time since treatment initiation, and those that did report such information were inconsistent with regard to the time points selected.

To resolve the first problem, the Panel reviewed all of the reported complications and collapsed those that were similar into summary categories (see Appendix 10 of the original guideline document) that are used in the graphs (see original guideline document Figures 3-5). For articles in which multiple individual complications were collapsed into a single category, the Panel assumed that there was no overlap between individual complications; thus, the percentage of patients in the summary category was the sum of the percentages for the individual complications. For example, if an article reported that 8%, 7%, and 6% of patients experienced nausea, vomiting, and diarrhea, respectively, the percentage of patients with a gastrointestinal complication would be estimated to be 21%. This method of aggregation yields upper-bound estimates of complication rates.

The Panel explored the alternative of assuming complete overlap between individual complications (yielding an estimate of 8% for gastrointestinal complications in the previously described example) but concluded that such lower-bound estimates would be less useful.

To resolve the second problem (i.e., the inconsistent reporting of the times at which complications were measured), the Panel decided to disregard timing and to simply use the highest rate reported for a given complication in each study.

With these two decisions -- to use upper-bound estimates of complication rates and to use the highest rate for a complication regardless of measurement time -- the Panel elected to show the highest rates of complications occurring for each patient group in each study. As a result, estimates should consistently err on the side of overstating actual complication rates.

It is worth noting that the most difficult complications to categorize were urinary incontinence and erectile dysfunction for which there were a large number of different measures. Ultimately, the Panel elected to use consolidated measures of severity for each of these outcomes.

Based on the data review and subsequent identification of the data limitations (see "Qualifying Statements"), meta-analysis was not deemed appropriate and further analysis and development of summary outcomes estimates were not undertaken.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

This document was written by the Prostate Cancer Clinical Guideline Update Panel of the American Urological Association Education and Research, Inc.®, which was created in 2001. The Practice Guidelines Committee (PGC) of the AUA selected the committee chairs. Panel members were selected by the chairs. Membership of the committee included urologists with specific expertise on this disorder. The mission of the committee was to develop recommendations that are analysis- or consensus-based, depending on panel processes and available data, for optimal clinical practices in the diagnosis and treatment of clinically localized prostate cancer.

The Panel developed guideline statements based on the limited data. As in the previous guideline, the present statements were graded with respect to the degree of flexibility in their application. Although the terminology has changed slightly, the current three levels are essentially the same as in the previous guideline. A "standard" has the least flexibility as a treatment policy; a "recommendation" has significantly more flexibility; and an "option" is even more flexible (see the field "Rating Scheme for the Strength of the Recommendations").

The Prostate Cancer Clinical Guideline Update Panel found wide variation in the outcomes for each treatment of prostate cancer such that it was necessary to describe most guideline statements as options. The reasons why no further treatment policies could be made were summarized previously. Nonetheless, *some* guideline statements were developed by the Panel—almost universally based on the results of randomized clinical trials (RCTs), many of which were published since the publication of the 1995 Guideline. As such, the guideline statements contain several stronger treatment policies based on these RCTs. In the guideline statements, the Panel selected the term "should" when the results of one or more RCTs do apply to the patient with clinical stage T1 to T2N0M0 disease and the term "may" when the results of one or more RCTs may apply to this patient population. (For example, if an RCT showed an improvement in metastasis-free survival for surgery when compared to watchful waiting in a population of men with organ-confined prostate cancer but did not provide an analysis strictly for low-risk disease, this observation was modified by the term "may" for patients with low-risk disease.)

The collective writing efforts of the Panel members and consultants resulted in this report.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

A "standard" has the least flexibility as a treatment policy, a "recommendation" has significantly more flexibility, and an "option" is even more flexible. These three levels of flexibility are defined as follows:

Standard: A guideline statement is a standard if: (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) there is virtual unanimity about which intervention is preferred.

Recommendation: A guideline statement is a recommendation if: (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) an appreciable but not unanimous majority agrees on which intervention is preferred.

Option: A guideline statement is an option if: (1) the health outcomes of the interventions are not sufficiently well known to permit meaningful decisions, or (2) preferences are unknown or equivocal.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

After Panel approval, a draft underwent peer review by 87 individuals, including members of the Practice Guidelines Committee, the AUA Board of Directors, and external prostate cancer experts. The Guideline was modified where the Panel deemed necessary in response to comments from 27 reviewers. A final version of the report was generated and the Panel voted for approval. This version was then forwarded, in turn, for approval of the Practice Guidelines Committee and the Board of Directors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Grades of the guideline statements (**Standard, Recommendation, Option**) are defined at the end of the "Major Recommendations" field.

Initial Evaluation and Discussion of Treatment Options with the Patient

Standard: An assessment of the patient's life expectancy, overall health status, and tumor characteristics should be undertaken before any treatment decisions can be made. [Based on review of data and Panel consensus.]

Treatment Alternatives

Standard: A patient with clinically localized prostate cancer should be informed about the commonly accepted initial interventions including, at a minimum, active surveillance, radiotherapy (external beam and interstitial), and radical prostatectomy. A discussion of the estimates for benefits and harms of each intervention should be offered to the patient. [Based on Panel consensus].

Treatment Recommendations

Treatment of the Low-Risk Patient

Option: Active surveillance, interstitial prostate brachytherapy, external beam radiotherapy, and radical prostatectomy are appropriate monotherapy treatment options for the patient with low-risk localized prostate cancer. [Based on review of data and Panel consensus.]

Standard: Patient preferences and health conditions related to urinary, sexual, and bowel function should be considered in decision making. Particular treatments have the potential to improve, to exacerbate or to have no effect on individual health conditions in these areas, making no one treatment modality preferable for all patients. [Based on review of data and Panel consensus.]

Standard: When counseling patients regarding treatment options, physicians should consider the following:

- Two randomized controlled clinical trials show that higher dose radiation may decrease the risk of PSA recurrence (Pollack et al., 2002; Zeitman et al., 2005)

- Based on outcomes of one randomized controlled clinical trial, when watchful waiting and radical prostatectomy are compared, radical prostatectomy may be associated with a lower risk of cancer recurrence, cancer-related death, and improved survival (Bill-Axelson et al., 2005). [Based on review of data and Panel consensus.]

Standard: Patients who are considering specific treatment options should be informed of the findings of recent high-quality clinical trials, including that:

- For those considering external beam radiotherapy, higher dose radiation may decrease the risk of PSA recurrence (Pollack et al., 2002; Zeitman et al., 2005)
- When compared with watchful waiting, radical prostatectomy may lower the risk of cancer recurrence and improve survival (Bill-Axelson et al., 2005). [Based on review of data and Panel consensus.]

Standard: For patients choosing active surveillance, the aim of the second-line therapy (curative or palliative) should be determined and follow-up tailored accordingly. [Based on Panel consensus.]

Treatment of the Intermediate-Risk Patient

Option: Active surveillance, interstitial prostate brachytherapy, external beam radiotherapy, and radical prostatectomy are appropriate treatment options for the patient with intermediate-risk localized prostate cancer. [Based on review of data and Panel consensus.]

Standard: Patient preferences and functional status with a specific focus on functional outcomes including urinary, sexual, and bowel function should be considered in decision making. [Based on review of data and Panel consensus.]

Standard: When counseling patients regarding treatment options, physicians should consider the following:

- Based on outcomes of one randomized controlled clinical trial, the use of neoadjuvant and concurrent hormonal therapy for a total of six months may prolong survival in the patient who has opted for conventional dose external beam radiotherapy (D'Amico et al., 2004)
- Based on outcomes of one randomized controlled clinical trial, when watchful waiting and radical prostatectomy are compared, radical prostatectomy may be associated with a lower risk of cancer recurrence, cancer-related death, and improved survival (Bill-Axelson et al., 2005)
- Based on outcomes of two randomized controlled clinical trials, higher dose radiation may decrease the risk of PSA recurrence (Pollack et al., 2002; Zeitman et al., 2005). [Based on review of data and Panel consensus.]

Standard: Patients who are considering specific treatment options should be informed of the findings of recent high-quality clinical trials, including that:

- For those considering external beam radiotherapy, the use of hormonal therapy combined with conventional-dose radiotherapy may prolong survival (D'Amico et al., 2004)
- When compared with watchful waiting, radical prostatectomy may lower the risk of cancer recurrence and improve survival (Bill-Axelson et al., 2005)
- For those considering external beam radiotherapy, higher dose radiation may decrease the risk of PSA recurrence (Pollack et al., 2002; Zeitman et al., 2005). [Based on review of data and Panel consensus.]

Standard: For patients choosing active surveillance, the aim of the second-line therapy (curative or palliative) should be determined and follow-up tailored accordingly. [Based on Panel consensus.]

Treatment of the High-Risk Patient

Option: Although active surveillance, interstitial prostate brachytherapy, external beam radiotherapy, and radical prostatectomy are options for the management of patients with high-risk localized prostate cancer, recurrence rates are high. [Based on review of the data.]

Standard: When counseling patients regarding treatment options, physicians should consider the following:

- Based on outcomes of one randomized controlled clinical trial, when watchful waiting and radical prostatectomy are compared, radical prostatectomy may be associated with a lower risk of cancer recurrence, cancer-related death, and improved survival (Bill-Axelson et al., 2005)
- Based on results of two randomized controlled clinical trials, the use of adjuvant and concurrent hormonal therapy may prolong survival in the patient who has opted for radiotherapy (Bolla et al., 2002; D'Amico et al., 2004). [Based on review of the data.]

Standard: High-risk patients who are considering specific treatment options should be informed of findings of recent high-quality clinical trials, including that:

- When compared with watchful waiting, radical prostatectomy may lower the risk of cancer recurrence and improve survival (Bill-Axelson et al., 2005)
- For those considering external beam radiotherapy, use of hormonal therapy combined with conventional radiotherapy may prolong survival (Bolla et al., 2002; D'Amico et al., 2004). [Based on review of the data.]

Additional Treatment Guidelines

Recommendation: Patients with localized prostate cancer should be offered the opportunity to enroll in available clinical trials examining new forms of therapy, including combination therapies, with the goal of improved outcomes. [Based on Panel consensus.]

Recommendation: First-line hormone therapy is seldom indicated in patients with localized prostate cancer. An exception may be for the palliation of symptomatic patients with more extensive or poorly differentiated tumors whose

life expectancy is too short to benefit from treatment with curative intent. The morbidities of androgen deprivation therapy (ADT) should be considered in the context of the existing comorbidities of the patient when choosing palliative ADT. [Based on Panel consensus.]

Definitions:

Grades of Guideline Statements

Standard: A guideline statement is a standard if: (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) there is virtual unanimity about which intervention is preferred.

Recommendation: A guideline statement is a recommendation if: (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) an appreciable but not unanimous majority agrees on which intervention is preferred.

Option: A guideline statement is an option if: (1) the health outcomes of the interventions are not sufficiently well known to permit meaningful decisions, or (2) preferences are unknown or equivocal.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation. Among the 436 articles selected as evidence, 352 were case series/reports, 3 were case-controls studies, 34 were cohort studies, 28 were controlled trials, 14 were database or surveillance studies, 1 was a review/policy statement, and 4 were of other design.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of clinically localized prostate cancer

POTENTIAL HARMS

- To some degree, each form of therapy has its own spectrum of complications. For example, hematuria is reported in several interstitial prostate brachytherapy and external beam radiotherapy series but is not reported in any surgical series. The Panel was unable to determine that any one therapy has a more significant cumulative overall risk of complications.
- Among the complications associated with treatments for clinically localized prostate cancer, those reported most often and with the greatest degree of variability were: incontinence and other genitourinary toxicity (i.e., irritative and obstructive urinary symptoms), hematuria, gastrointestinal toxicity, proctopathy, and erectile dysfunction (impotence). Due to their salience, the Panel devoted special attention to these complications by highlighting findings from several of the extracted case series. (See details in the original guideline document.)

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This report is intended to provide medical practitioners with a consensus of principles and strategies for the treatment of clinically localized prostate cancer. The report is based on current professional literature, clinical experience, and expert opinion. It does not establish a fixed set of rules or define the legal standard of care, and it does not preempt physician judgment in individual cases.
- The present Guideline suffered the same problem as the original 1995 version: the data are still insufficient to provide adequate summary outcomes estimates for the target patient(s). (See the original guideline document for specific data limitations.)
- The lack of and inconsistencies in the data were also, in part, due to the design and process of the data extraction. The strict inclusion criteria used to define the body of literature extracted may have caused potentially useful studies to be excluded from the analysis. For example, many radiotherapy studies reported outcomes for patients with clinical stage T1 to T3 disease. If the patients with T1/T2 disease could not be separated from those with T3 disease, this series was rejected from the extraction process because of "T3 contamination." In addition, some of the variation in outcomes may have been due to the variation in the groups examined as data were extracted by patient groups based on such characteristics as stage, PSA level, and grade.
- A quantitative synthesis of the results of the quality-of-life literature also was impossible due to cross-study diversity. (See the original guideline document for more detailed information.)

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Prostate Cancer Clinical Guideline Update Panel. Guideline for the management of clinically localized prostate cancer: 2007 update. Linthicum (MD): American Urological Association Education and Research, Inc.; 2007. 82 p. [123 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1995 (revised 2007 Jan)

GUIDELINE DEVELOPER(S)

American Urological Association Education and Research, Inc. - Medical Specialty Society

SOURCE(S) OF FUNDING

The American Urological Association (AUA) is the sole source of funding.

GUIDELINE COMMITTEE

Prostate Cancer Clinical Guidelines Panel Members and Consultants

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Each member of the committee provided a conflict-of-interest disclosure to the American Urological Association (AUA).

GUIDELINE STATUS

This is the current release of the guideline.

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GUIDELINE AVAILABILITY

Electronic copies: Available from the [American Urological Association \(AUA\) Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

Not stated

PATIENT RESOURCES

None provided

NGC STATUS

This summary was completed by ECRI on March 26, 1999. The information was verified by the guideline developer as of May 14, 1999. This NGC summary was updated by ECRI Institute on November 5, 2007. The updated information was verified by the guideline developer on November 12, 2007.

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